AMERICAN LASERS, INC. K061850

SEP 29 2006

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
MINI-YAG LASER

IN ACCORADANCE WITH THE SAFE MEDICAL DEVICES ACT OF 1990, 21CFR 807.92, THE FOLLOWING IS A SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION ON WHICH THE SUBSTANTIAL EQUIVALENCE DETERMINATION IS BASED.

THE SAFETY AND EFFECTIVENESS OF THE MINI-YAG LASER DERIVES FROM A DETERMINATION OF SUBSTANTIAL EQUIVALENCE TO THE PREDICATE DEVICES LISTED BELOW.

APPLICANT: AMERICAN LASERS, INC.
300 EAST MAIN STREET
ALHAMBRA, CA 91801
C/O DAVID K. QUON, PRESIDENT

DATE PREPARED: SEPTEMBER 22, 2006

MODEL:
TRADE NAME: MINI-YAG LASER
COMMON NAME: Q-SWITCHED Nd:YAG LASER WITH FREQUENCY DOUBLER.

PRODUCT CODE: GEX

PANEL: 79

C.F.R. SECTION: 878.4810

CLASSIFICATION PANEL: GENERAL AND PLASTIC SURGERY.

CLASSIFICATION:
MEDICAL DEVICE CLASS: REGULATORY CLASS II
LASER SAFETY CLASS: CLASS IV LASER PRODUCT

PREDICATE DEVICES:
PALOMAR Q-YAG LASER SYSTEM (K023967)
MEDLITE Q-SWITCHED Nd:YAG LASER (K022709 & K983054)
MEDLITE C3 Q-SWITCHED Nd:YAG LASER (K011677)
MEDLITE C6 Q-SWITCHED Nd:YAG LASER (K014234)
SPECTRA-VRM Q-SWITCHED Nd:YAG LASER (K000317)
LIGHT AGE Q-CLEAR LASER (K033259)

DESCRIPTION:

THE MINI_YAG LASER IS A Nd:YAG LASER WITH EMITTED WAVELENGTH AT 1064 NANOMETERS. WITH THE FREQUENCY DOUBLER INSTALLED, A 532 NANOMETER WAVELENGTH IS EMITTED. THE 1064 NM IS IN THE NEAR-INFRARED PORTION OF THE SPECTRUM, WHILE THE 532 NM IS VISIBLE AS A GREEN LIGHT. LASER ENERGY IS DELIVERED DIRECTLY TO THE SKIN LESION VIA THE HANDPIECE, WHICH PRODUCES A CIRCULAR BEAM ON THE SKIN. THE MINI-YAG LASER IS EQUIPPED WITH SAFETY FEATURES IN CONFORMANCE WITH 21CFR PART 1040.

INTENDED USES:

1. FOR INCISION, EXCISION, ABLATION, AND VAPORIZATION OF SOFT TISSUE FOR GENERAL DERMATOLOGY.
2. THE 1064 NM WAVELENGTH IS INDICATED FOR:
   DARK INK TATTOO REMOVAL.
   TREATMENT OF PIGMENTED LESIONS SUCH AS NEVUS OF OTA.
   REMOVAL OR LIGHTENING OF HAIR.
   TREATMENT OF COMMON NEVI
3. THE 532 NM WAVELENGTH IS INDICATED FOR:
   REMOVAL OF LIGHT INK (RED, TAN, PURPLE, AND ORANGE) TATTOOS
   TREATMENT OF COMMON NEVI
   TREATMENT OF CAFÉ AU-LAIT SPOTS.
   TREATMENT OF SEBORRHEIC KERATOSES
   TREATMENT OF VASCULAR LESIONS, INCLUDING FACIAL AND LEG VEINS, TELENGIECTASIAS, ANGIOMAS, HEMANGIOMAS, PORT-WINE STAINS, AND MOST PIGMENTED LESINS SUCH AS LENTIGINES, AND EPHELIDES.

SAFETY AND EFFECTIVENESS:

THE MINI-YAG LASER FROM AMERICAN LASERS, INC. HAS THE SAME WAVELENGTHS, THE SAME SPOT SIZE, THE SAME PRINCIPLE OF OPERATION, ESSENTIALLY THE SAME FLUENCE LEVELS, AND THE SAME INTENDED USE AS THE PREDICATE DEVICES. THE MINI-YAG LASER DOES NOT RAISE NEW QUESTIONS OF SAFETY OR EFFECTIVENESS, AND IS SUBSTANTIALLY EQUIVALENT TO THE PREDICATE DEVICES LISTED ABOVE.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 2006

American Lasers, Inc.
% Mr. David K. Quon, MD
President
300 East Main Street
Alhambra, California 91801

Re: K061850
Trade/Device Name: Mini-Yag
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 28, 2006
Received: July 31, 2006

Dear Dr. Quon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061850

Device Name: MINI-YAG

Indications For Use: THE MINI YAG LASER SYSTEM FROM AMERICAN LASERS, INC. IS A SOLID-STATE Nd:YAG LASER SYSTEM THAT PROVIDES TWO WAVELENGTHS, 1064nm AND 532nm FOR THE REMOVAL OF BLACK AND BLUE TATTOOS AS WELL AS SUPERFICIAL EPIDERMAL PIGMENTED LESIONS AND SMALL VASCULAR LESIONS.

TATTOOS REMOVAL:
THE **532nm** WAVELENGTH CAN BE USED TO REMOVE RED, TAN, PURPLE, AND ORANGE TATTOO INKS.
THE **1064nm** WAVELENGTH CAN BE USED TO REMOVE DARK (BLACK) AND BLUE COLOR INKS.

THE **532nm** WAVELENGTH CAN ALSO BE USED FOR REMOVAL OF SUPERFICAL BENIGN, PIGMENTED SKIN LESIONS SUCH AS LENTIGINES AND CAFÉ-AU-LAIT, TREATMENT OF COMMON NEVI, AND SEBORRHEIC KERATOSES.
ALSO THE **532nm** WAVELENGTH CAN BE USED TO REMOVE SMALL VASCULAR LESIONS SUCH AS TELAGIECTASIAS, SMALL FACIAL AND LEG VEINS, ANGIOMAS, HEMANGIOMAS, PORT-WINE STAINS, AND MOST OTHER BENIGN PIGMENTED LESIONS SUCH AS LENTIGINES AND EPHELIDES.
THE **1064nm** WAVELENGTH CAN ALSO BE USED TO TREAT PIGMENTED LESIONS SUCH AS THE NEVUS OF OTA, REMOVAL OR LIGHTENING OF HAIR, TREATMENT OF COMMON NEVI.

Prescription Use XX AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061850